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Therapeutic Products Directorate

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Direction des produits thérapeutiques

NOTRE MISSION : Nous contribuons à l'amélioration de la santé des Canadiens et à l'efficacité du système de soins de santé en réglementant les produits pharmaceutiques et les matériels médicaux et en offrant aux Canadiens un accès à l'information pour qu'ils puissent faire des choix éclairés

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TO/À

Name/Nom: Dr. Rick Doblin Date: 17 March 2009

Organization/Organisme: Multidisciplinary Association for Psychedelic Studies

Tel./Tél.: 617-484-8711 Fax/Télécopieur: 617-484-8427

No. of Pages, including this page/Nbre pages, incluant cette page: 2

FROM/DE

Name/Nom: *Elizabeth Komsta, M.Sc., Ph.D.* E-Mail/Courier électronique elizabeth_komsta@hc-sc.gc.ca

Tel./Tél.: 613 - 941-0570 Fax/Télécopieur: 613 - 952 - 9656

TITLE	A/Manager - Clinical Trials Group I / Gestionnaire/i - Programme des essais cliniques Groupe II	TITRE
Division	Office of Clinical Trials / Bureau des essais cliniques	Division
Directorate	THERAPEUTIC PRODUCTS DIRECTORATE / DIRECTION DES PRODUITS THÉRAPEUTIQUES	Direction
Room	5073	Pièce
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Postal Code	K1A 0K9	Code postal

Website/site Web : http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html/
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_f.html

MESSAGE

Clinical Trials Manual/Manuel d'essais cliniques

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_intro-eng.php or /cta_intro-fra.php

Release of Protocol Safety and Efficacy Assessment Template-Clinical Trial Application (PSEAT-CTA)/
Diffusion du Modèle d'évaluation de l'innocuité et de l'efficacité des protocoles - Demande d'essai clinique (MEIEP-DEC)

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/templates-modeles/pseat_cta_meiep_doc-eng.php or /pseat_cta_meiep_doc-fra.php

Health Canada / Santé Canada

Therapeutic Products Directorate
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Your file / Votre référence

Our file / Notre référence

9427-M2544-21C

17 March 2009

Rick Doblin PhD
President
Multidisciplinary Association for
Psychedelic Studies
3 Francis Street,
BELMONT, Massachusetts
USA 02478-2218
(617) 484-8711

No Objection Letter RE: Protocol # MP-4

Dear Dr. Doblin:

I am pleased to inform you that the information and material to support your Clinical Trial Application for **MDMA**, control number **127822**, received on February 16, 2009, have been reviewed and we have no objection to your proposed study.

I would remind you of the necessity of complying with the *Food and Drug Regulations*, Division 5, in the sale of this product for clinical testing. In addition, the regulations impose record keeping responsibilities on those conducting clinical trials.

You are also reminded that all clinical trials should be conducted in compliance with the Therapeutic Products Directorate's *Guideline for Good Clinical Practice*.

Please note that for drugs marketed in Canada and in clinical trials, any serious and unexpected adverse drug reaction occurring inside or outside Canada should be reported to both MHPD and TPD until completion of the trial then the reports should be send to MHPD only.

Should you have any questions concerning this letter, please contact the Office of Clinical Trials (613) 941-2132.

Yours sincerely,

Elizabeth Komsta, M.Sc, Ph.D.
A/Manager - Clinical Trials Group II
Office of Clinical Trials

EK/en

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